REMARKS

Entry of the foregoing amendment is requested to place new claims 13-23 in the application for consideration by the Examiner.

The courteous telephone interview granted to the undersigned counsel by the Examiner is acknowledged with appreciation. In that interview, the Examiner instituted an election of species requirement between the several species directed to particular side effects as set forth in claims 4, 5, 6, 7, 8, and 9. In response, Applicants elect the specie of claim 5 directed to fatigue as a side effect. The election is made with traverse and reconsideration is requested. It is noted that claim 1 currently in the application is generic to all species and new claim 13 submitted herewith is generic to all species set forth in the claims. Claims 13-15, 17 and 23-26 read on the elected species.

In the telephone interview, the Examiner brought to Applicants' attention the existence of new prior art being considered by the Examiner. This new prior art is U.S. Patent 6,403,640 B1, published patent application U.S. 2001/0011097 A1, and published U.S. patent application U.S. 2002/0009421 A1. Copies of this prior art are submitted with this response and listed in an Information Disclosure Statement

In addition, Applicant wishes to direct the Examiner's attention to published PCT application WO 00/38716 to McKearn. This PCT publication was published July 6, 2000, subsequent to Applicants' filing date so that the PCT publication is not prior art against this application. However, in view of the relationship of the subject matter, the PCT publication is presented for the Examiner's consideration in this application. This PCT publication is also included in the enclosed Information Disclosure Statement.

By this amendment, independent claim 13 is substantially revised to advance prosecution in this application. In particular, claim 13 is now placed in improvement form to better emphasize the invention. As will be appreciated from Applicants' specification, the invention concerns use of selected COX-2 inhibitors to treat the side effects caused by radiation therapy for patients requiring such therapy such as in the treatment of cancer. The claim now recites that the improved method comprises administering to the subject a side effect reducing amount of a selective cyclooxygenase-2 as the effective agent to treat the side effect which is radiation caused. Further, the side effects now include gastrointestinal effects, fatigue, diarrhea, rectal bleeding, urinary frequency, dysuria, and nocturia. Support for the side effects may be found on page 3 of the specification.

Of the dependent claims, claims 14-19 correspond to cancelled claims 2-7, claims 19-22 are specific to side effects listed in claim 13, claims 23-25 correspond to cancelled claims 10-12 and new claim 26 is presented to indicate that the side effects are reduced by at least 25% with support at page 6, paragraph 24. Accordingly, entry of these claims is requested.

It is further submitted that the claims presented herewith are patentable over all prior art of which Applicant is aware including the new prior art mentioned by the Examiner.

U.S. Patent 6,403,640 B1 to Stoner et al. is directed to the use of a COX-2 selective inhibitor for the treatment of chronic prostititis or chronic pelvic pain syndrome. There is no mention in this patent that the prostititis was caused by radiation. Applicants' claims are not now directed to reducing the symptoms of prostititis and cystitis but are directed to other radiation-caused side effects. Accordingly, the claimed invention is clearly different from

what is disclosed in this patent. For these reasons, Applicants submit that the claims are clearly patentable over Stoner et al.

Published Application 2001/0011097 A1 to Sonis et al. is directed to a combination method of reducing or inhibiting oral mucositis in a patient. The method comprises administering to the patient first and second different therapeutic agents wherein the first therapeutic agent is an NSAID, an inflammatory cytocine inhibitor, or a mass cell inhibitor, and the second therapeutic agent is an inflammatory cytocine inhibitor, a mass cell inhibitor, an MMP inhibitor, an NSAID or an NO inhibitor. COX-2 and COX-1 are disclosed as one of the first or second agents. The reference also discloses in paragraph 37, on page 3, that COX-2 inhibitors are especially useful where the invention is used to treat mucositis in cancer patients undergoing chemotherapy or radiation therapy because of the gastrointestinal tolerability of these inhibitors. It is clear from the overall disclosure in this patent, however, that the COX-2 inhibitors are used only in the combination therapy recited in the patent. and are used only in the treatment of oral mucositis. Since Applicants' claims exclude oral mucositis treatment, the claims are clearly patentable thereover.

Published U.S. Application U.S. 2002/0009421 A1 discloses a method of relieving pain, fever, or inflammation in a subject suffering from sunburn or other skin injury resulting from exposure to UV radiation, the method comprising orally administering to the subject a therapeutically effective amount of a selective COX-2 inhibitor drug. As will be appreciated, this patent is concerned simply with the treatment of sunburn caused by UV rays and has nothing to do with the radiation therapy treatment of this invention. Further, Applicants' claims are not now directed to the treatment of dermatitis problems so the claims clearly distinguish from this reference.

It is therefore submitted that the new claims submitted in this application are clearly patentable over all the prior art of which Applicant is aware and are believed to be in condition for allowance. Accordingly, such action is respectfully solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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